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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,541	07/27/2001	Carl D. Meinhart	1279-368	8568

7590 06/03/2004
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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,541

Applicant(s)

MEINHART ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed on 2/11/2004 has been received and entered into record and considered.

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The currently amended claim recites a new matter, "*an interaction region*" not as claimed as originally filed application. The original claim 1, recites "*a sample chamber*" in component (b) and (c), whereas the instant amended claim changes this *sample chamber* to "*an interaction region*". In light of specification, the original "*sample chamber*" is defined as the component 80 in Figure 6. (page 9, section 0040) This sample chamber is formed by connect the top chip InP TLCS 10 to the Si-biofluidic chip 14. (See Figure 5 and 6) However, applicant now intends to change this sample chamber to "*an interaction region*" as the component 48 shown in Figure 4. This is a new matter and would not be considered and should be cancelled.

With respect to claim 10, last line, "define a sample region" is also a new matter. There is no support in the specification indicating a "sample region", rather applicant consistently uses "sample cavity" in the specification.

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 9, “an interaction region separate and physically spaced from said phase control section” is vague and confusing. This region is not separate and physically spaced from phase control section. It is a continuous section connecting phase control with the interaction region. (See Figure 4 and 5) Similarly, claims 3, 10 and 22 share the same problem.

With respect to claim 1, step (b), line 3, “for receiving a fluid and discharging effluent” is vague and confusing. It is not clear how the “interaction region” can “receive a fluid and discharging effluent”.

With respect to claim 4, “said inlet and outlet are formed by microchannels through the body of said chip” lacks antecedent basis. Similarly, claim 17 shares the same problem as claim 4.

With respect to claim 10, last line, “sample region” is vague and indefinite. It is not clear whether this region refers to the “interaction region”. Similarly, claims 20 and 21 share the same problem.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 1, 2, 4-16, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lading et al. (WO 99/37996) in view of Beregovski et al.. (Sensors and Actuators 1998 53: 116-124)

Lading et al. disclose a sensor chip device in detecting analytes of interest. The sensor chip comprises a pair of lasers comprising a reference laser (7) and a sensor laser (7'), with gain region (12), mirrors (11), sample cavity (8, 8') having an inlet for receiving a fluid and an outlet for discharging effluent from a microfluidic system (13) and exposing to the evanescent field of laser sensor, heterodyne detector (4) at the juncture of the reference and sensor coherent light output sections, for detection the change of refractive index of fluid in the sample chamber. (See Figure 2-4) Lading et al. also teach loading the surface of sensing sensor with a specific binding partner as an adsorbent for molecules to be diagnosed (claims 12-14), the microfluidics system (13) for passing a sample to the waveguides (Figure 2). The sample cavity is between the gain and mirror regions. (See components 7 and 8 in Figure 2 and sections 14a-14b as sample cavities versus component 12 gain region in Figure 3) However, Lading et al. do not specifically

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disclose placing a phase section in its sensor laser. Beregovski et al. teach using laser sensor waveguides comprising phase control, gain and grating sections in measuring environmental chemicals (Figure 1) and placing Bragg grating reflector having different sampled periods in its laser sensor (Figure 1). Such a waveguide would provide a sensor with high sensitivity, compact, low-cost and real-time sensors. (See Abstract and Introduction) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device with Lading et al. where the sample chamber separate from the laser sensor, with the laser waveguides having phase control section as taught by Beregovski et al., since it is known in the art to have higher sensitivity and lower cost for the detection of analyte in interest and the artisan would have been motivated to incorporate the phase control in the sensors.

8. Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lading et al. and Beregovski et al. and further in view of Seul et al. (USP 6387707)

Lading et al. and Beregovski references have been discussed above which fail to recite using dielectrophoretic electrodes. Seul et al. disclose using dielectrophoretic properties of various cells as basis for increase particle concentration and particle separation. (Col. 39, line 19-29) Therefore, it would have been obvious to one skill in the art at the time the invention was made to have provided the modified optical device of Lading et al. with the dielectrophoretic electrode as taught by Seul et al., in order to increase the concentration of molecules to be diagnosed adjacent to the adsorbent of the sample chamber.

9. Claims 17-19, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lading and Beregovski, and further in view of Bach et al. (US20020110839)

Both Lading and Beregovski et al. references have been discussed but fail to teach using series laser sensor for multiple detection purposes. Bach et al. teach using microarray of optical waveguides connected in series to detect multiple screening. (Section 0035-0036)

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Bach et al. teach connect inlet/outlet on sensors in series to inlet/outlet of other sensor waveguides to save time, expense and labor. (See Section 0035-0036; Figure 2 and Figure 5) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the instant invention with series of connected sensor as taught by Bach et al. to detect multiple analytes in interests to save time, expense and labor cost.

Response to Applicant's Arguments

Applicant argues that Beregovski et al. reference is not a proper secondary reference because they do not have an interaction region separate and physically spaced from a phase control section as recited in the newly amended claim. Applicant's argument has been considered but is not persuasive. First, Examiner had drawn applicant's attention that the newly amended "interaction region" is a new matter and should be cancelled in pursuant to 35 USC §112. Second, Examiner points out in this Office Action that the sample cavity is *NOT* separate and physically spaced from the phase control. Accordingly to Figure 3 and 4, the sample cavity *connects* to the phase control section. Third, Beregovski et al. reference provides the advantages and suggestions of using phase control section on the sensor for sensitivity and cost-effectiveness. Therefore, Beregovski et al. reference is used to incorporate a phase control section to the sensor to the Lading's biochip where the arrangement of the mirror, gain and the added phase control sections are separate from the interaction regions. (See Figures 2-4) Fourth, the Office position in interpreting the Lading's device is that both the laser sensor and the microfluidic channels formed the sample cavity, thus read on the instant invention. (See Lading et al. Figure 2 compared to the Figure 6 (upside down) of instant invention)

Conclusion

10. No claim is allowed.

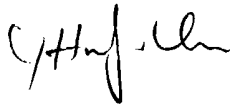
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

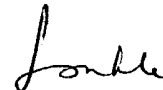
Jacob Cheu



Examiner

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May 24, 2004



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06/01/04